DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 93P–0277]

Medical Devices; Reclassification and Codification of Neodymium:Yttrium:Aluminum:Garnet (Nd:YAG) Laser for Peripheral Iridotomy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to Intelligent Surgical Lasers, Inc. (ISL), (now doing business as Escalon Medical Corporation), reclassifying the Neodymium:Yttrium:Aluminum:Garnet (Nd:YAG) Laser for use in peripheral iridotomy from class III to class II (special controls). Accordingly, the order is now being codified in the Code of Federal Regulations (CFR) as described below.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**]. The reclassification was effective August 13, 1999.

FOR FURTHER INFORMATION CONTACT: Morris Waxler, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Devices Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug

Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act, formerly 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

FDAMA added paragraph (f)(2) in section 513 to the act, which also addresses classification of postamendments devices. New paragraph (f)(2) in section 513 of the act provides that, upon receipt of a ''not substantially equivalent'' determination, a 510(k) applicant may request FDA to classify a postamendments device into class I or class II. Within 60 days from the date of such a written request, FDA must classify the device by written order. If FDA classifies the device into class I or II, the applicant has then received clearance to market the device and it can be used as a predicate device for other 510(k)'s. It is expected that this process will be used for low risk devices. This process does not apply to devices that have been classified by regulation into class III—i.e., preamendments class III devices, or class III devices for which a PMA is appropriate.

Under section 513(f)(3)(B)(i) of the act, formerly section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

On July 27, 1993, FDA filed the reclassification petition submitted by ISL, requesting reclassification under section 513(f)(3) of the act, of the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy from class III to class II. This is a postamendments device that was automatically classified into class III.

FDA consulted with the Ophthalmic Devices Panel (the Panel). During an open public meeting on October 28, 1993, the Panel recommended that FDA reclassify the Nd:YAG laser for peripheral iridotomy from class III to class II. The Panel considered clinical studies of Nd:YAG iridotomy that report few risks to health and those that are reported have been clearly identified. The incidence rates for iridotomy closure, vision loss due to progression of laser-induced lens or corneal damage, focal corneal opacities, mild iritis, and hyphema are either lower than those for argon laser surgery or conventional surgical iridotomy, or are self-limiting and not persistent. A few rare complications (malignant glaucoma, lens-induced endophthalmitis, monocular glaucoma, lens rupture) have been reported. The risks of damage to the corneal endothelium, the lens, and the retina are slight. The Panel believes these risks can be kept minimal by ensuring proper device design of laser beam accuracy and precision.

FDA considered the Panel's recommendations and tentatively agreed that the generic type of device, Nd:YAG laser for peripheral iridotomy, be reclassified from class III to class II. FDA recommended that the generic designation of the device be changed from Nd:YAG laser for posterior capsulotomy to ND:YAG laser for posterior capsulotomy and peripheral iridotomy.

Subsequently, in the **Federal Register** of March 8, 1996 (61 FR 9373), FDA issued the Panel's recommendation for public comment.

After reviewing the data in the petition and presented before the Panel, and after considering the Panel's recommendation, FDA, based on its and the Panel's review, issued an order to the petitioner on August 13, 1999, reclassifying the Nd:YAG laser for posterior capsulotomy, and substantially equivalent devices of this generic type, from class III to class II, with design parameters as the special controls. Additionally, FDA changed the generic designation of the device

from Nd:YAG laser for posterior capsulotomy to Nd:YAG laser for posterior capsulotomy and peripheral iridotomy. FDA believes the risks mentioned above can be kept minimal by ensuring proper device design of the laser beam accuracy and precision, and through proper device labeling disclosures whereby the surgeon can control the risk of intraocular pressure rise through available, established medical treatments.

Accordingly, as required by § 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the generic Nd:YAG laser for posterior capsulotomy and peripheral iridotomy from class III into class II. In addition, FDA is issuing the notice to codify the reclassification of the device by revising 21 CFR 886.4392.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The Commissioner of Food and Drugs therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this notice will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public. Therefore, no burden is placed on the public.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

1. The authority citation for 21 CFR part 886 continues to read as follows:

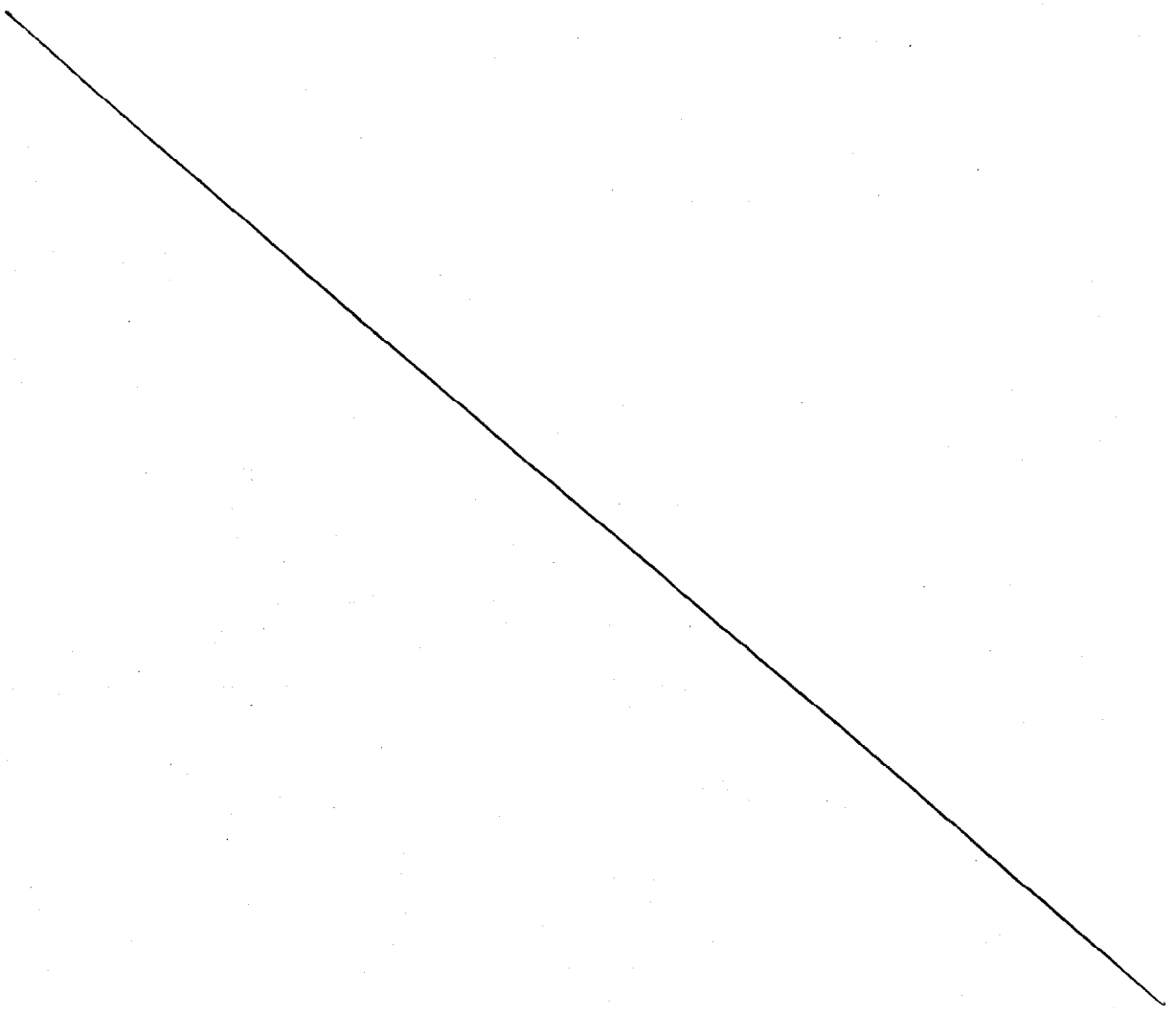
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 886.4392 is revised to read as follows:

§ 886.4392 Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.

(a) *Identification.* The Nd:YAG laser for posterior capsulotomy and peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser intended for disruption of the posterior capsule or the iris via optical breakdown. The Nd:YAG laser generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the invisible Nd:YAG laser radiation on or in close proximity to the target tissue.

(b) *Classification.* Class II (special controls). Design Parameters: Device must emit a laser beam with the following parameters: wavelength = 1064 nanometers; spot size = 50 to 100 micros;



pulse width = 3 to 30 nanoseconds; output energy per pulse = 0.5 to 15 millijoules (mJ); repetition rate = 1 to 10 pulses; and total energy = 20 to 120 mJ.

Dated: 1/24/00
January 24, 2000

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